#31

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

OCT 20 2003

HARRY B. SHUBIN
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BOULEVARD
ARLINGTON, VA 22201

In re Application of
Werner Weitschies et al
Serial No: 08/894,767
Filed: February 23, 1998
Attorney Docket No.: SCH1526

PETITION DESCISION

This is in response to applicants' petition under 37 CFR 1.144 filed March 3, 2000.

BACKGROUND

A review of the file history shows that this application was accepted under 35 U.S.C. 371 on February 23, 1998. The application as filed contained claims 1-38. In a first Office action mailed December 17,1999, an examiner from Art Unit 1616 set forth a lack of unity requirement under 35 U.S.C. 121 and 372 dividing the claims into two groups and requiring an election of species for any elected group, as follows:

Group I, claims 1-25, drawn to in vitro methods of performing an immunoassay of a liquid.

Group II, claims 26-38, drawn to in vivo method of detecting a ferromagnetic substance.

The species were defined as compounds comprising various ferromagnetic substances, various structure-specific substances such as antibodies, cytokines receptors etc.

In response to this lack of unity, applicants responded with an election on January 24, 2000, electing Group I with traverse. Applicants did not elect a species as required and argued that there is no search burden and that both Groups have a special technical feature in that the underlying measurements are based on remanent magnetization.

Repln. Ref: 11/04/2003 NVILLARI 0006423900
DA#:133402 Name/Number:08894767
FC: 9204 $130.00 CR

Since no species was elected the examiner in Art Unit 1616 sent out a non responsive letter on March 24, 2000, requiring applicants to elect a species and identify the claims readable on the elected species as required by the original lack of unity.

Applicants replied by adding claim 39 and electing a magnetite-labeled anticollagen III and elected a ferromagnetically shielded chamber with a detector, in which remanence is measured (e.g. SQUID). Applicant again presented arguments concerning the traversal.

Since the election was to a specific biological material the application was transferred to an examiner in Art Unit 1641. The first office action of the new examiner, mailed July 5, 2000, was to revise the Lack of Unity requirement. This new lack of unity divided the claims into four groups as follows:

Group I, claim(s) 1, 2, 4, 5, 8-25, 39, drawn to a method of qualitative and/or quantitative detection of analytes in liquid/solid phases using ferromagnetic or ferrimagnetic substances as labels.

Group II, claim(s) 3, 6, 7, drawn to a method of quantitative and/or qualitative detection of analytes in immunoassays or other binding assays using magnetic field sensors and an external magnetic field.

Group III claim(s) 26, 32, 36-38, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body.

Group IV claim(s) 27-31, 35, drawn to a method for detection of ferromagnetic substances that that are introduced into a human body or applied to a human body using external magnetic field and magnetic field sensors.

The examiner stated that Groups (I and II) or (III and IV) lack the same feature which is the use of external magnetic field and magnetic field sensors. Groups (I or II) and Groups (III or IV) differ because the method of Group III or IV are applied to a human body or introduced into the human body.

Applicants replied on August 4, 2000, by electing Group I with traverse including claims 1, 2, 4, 5, 8-25 and 39. Applicant's traversal stated that the "special technical feature" is the use of ferromagnetic or ferromagnetic substances as labels to detect substances and that it did not matter whether the use was *in vitro or in vivo*.

The first action on the merits was mailed on October 25, 2000. In the action the examiner responded that the traversal was not persuasive since the special technical feature alleged by applicants is known in the art as taught by JP 3220442. The Japanese patent teaches a method of determining concentrations of antibodies or antigens binding with an analyte in a liquid sample, comprising suspending the magnetic fine particles fixed with the antibody or antigen binding specifically with the analyte, causing agglutination of the magnetic fine particles by antigen-antibody reaction, then applying a magnetic field to a liquid containing the agglutinate component which results in aligning the magnetic fine particles, turning off the magnetic field and then measuring the remanent magnetic flux density of the agglutinated matter. The examiner held claims 3, 6, 7, and 26-38 non-

elected and made the lack of unity FINAL. The rejections in this first action on the merits included 35 U.S.C. 112, second paragraph, rejections on claims 1, 2, 4, 8-25 and 39; 35 U.S.C. 102(b) rejection of claims 1, 2, 4, 5 as anticipated by JP 3220442; 35 U.S.C. 102(b) rejection of claims 19 and 22-24 as anticipated by EP 0180384; 35 U.S.C. 102(b) rejection of claims 1, 2, 4, 5, 8, 11-12 and 18 as anticipated by US 5,164,297; 35 U.S.C. 103(a) rejection of claims 16-18 over JP 3220442 in view of EP 0180384; obviousness type double patenting of claims 1, 9, 10, and 20 over claims 1, 15 and 20 of US 6,027,946. The examiner stated that claims 13-15 and 21 were free of prior art.

Applicants filed a reply on February 2, 2001, which included amending claims 1-18, 22-32 and 35-39, canceling claims 19-21 and 33-34, and responding to all the rejections, and maintaining the traversal of the lack of unity by restating the arguments of August 4, 2000. Applicant amended claims 1-3 to include the limitation of a heterogeneous immunoassay.

The examiner mailed a Final Office action to applicants on May 11, 2001. Claims 8, 11-18, 25 and 39 were stated as being free of prior art. The 35 U.S.C. 102(b) rejection over US 5,164,297 was withdrawn, as was the 35 U.S.C. 112, second paragraph, rejection. The 35 U.S.C. 102(b) rejections over claims 1, 2, 4 and 5 as anticipated by JP 3220442 and claims 22-24 as anticipated by EP 0180384 were maintained, as was the 35 U.S.C. 103(a) rejection of claims 16-18 over JP 3220442 in view of EP 0180384 and the obvious double patenting rejection. A new rejection under 35 U.S.C. 112, first paragraph, was made over claims 1, 2, 4, 5, 8-18, 22-25, and 39 for lack of enablement.

Applicants replied on July 13, 2001, by proposing amendments to claims 1 and 3 which were entered by the examiner. Applicants addressed all the issues that were pending, maintaining the traversal of the lack of unity holding. The examiner responded to the arguments and mailed out an advisory action to applicants on August 28, 2001, in which the rejections under 35 U.S.C. 112, first paragraph and for obvious double patenting (in view of a proper terminal disclaimer) were withdrawn.

On October 12, 2001, a Notice of Appeal was filed.

On March 19, 2002, Applicants submitted a RCE and an amendment of claims 1-3 to change a limitation to a homogeneous immunoassay, and addressed the rejections and the lack of unity again. Applicants in this traversal restated previous arguments and added a further statement that the office action did not suggest what process other then an external magnetic field could be employed.

The examiner mailed a new non-final office action to applicants on June 18, 2002. The examiner addressed the lack of unity and special technical feature and again cited JP 3220442. Some additional 35 U.S.C. 112, second paragraph, rejections were made on claims 1, 2, 4, 5, 8-18 22-25 and 39 and an objection was made to claim 22. All the 35 U.S.C. 102(b) and 35 U.S.C. 103(a) rejections were withdrawn

On September 18, 2002, an amendment was filed which amended claims 1-2, 5, 11 and 36, added claims 40-42 and canceled claim 4. The new claims, dependent on claim 1,

were placed in Group I and examined. At this point in the prosecution claims 1-3, 5-18, 22-32, 35-39 and newly added claims 40-42 were pending and claims 1, 2, 5, 8-18, 22-25, and 39-42 read on the elected group. Again applicant traversed the lack of unity holding.

On December 3, 2002, the examiner mailed a Final Office action to applicants and replied to applicants' continued traversal of the lack of unity holding. In the Office action the examiner also objected to claim 22 as being dependent on a non elected claim and rejected claims 1, 2, 5 8-18, 22-25 and 39-42 under 35 U.S.C. 112, second paragraph. The elected claims continued to be deemed free of prior art.

An After Final amendment filed by applicants on March 3, 2003, concurrently with this petition, has not yet been considered by the examiner. It is also noted that a second RCE was filed on September 9, 2003, will be processed subsequent to mailing of this decision.

DISCUSSION

Applicants have argued burdensome search, which is not a criteria for a lack of unity. Applicants have also stated that one "special technical feature" is that all four groups employ the use of ferromagnetic or ferrimagnetic substances as labels. However, as the examiner has shown by citing JP3220442 this technical feature is known in the art and therefore this is not a special technical feature which defines a contribution to the art and thus cannot support Unity.

Applicants have stated that there is no difference in detecting the labeled substances either *in vitro or in vivo*. The claims are directed to methods. It is the scope of the methods and the steps in the methods, which must be considered in determining whether or not the methods have unity. The method steps for the detection of an analyte in a liquid or solid phase homogenous immunoassay are generally found as follows: (i) labeling a structure specific substance with ferromagnetic or ferromagnetic substances, (ii) adding the magnetic labeled structure specific substance to a sample to be measured, (iii) magnetizing the sample to be measured with an external magnetic field, and (iv) measuring the remanence of the magnetism after the magnetic field is turned off. The method steps for detection in an organism are the same. There are no additional steps to the method for detection as seen in claim 27. The method of detecting an analyte *in vitro* is the same method with the same steps as detecting an analyte in an organism (*in vivo*). Claim 3, from which steps (i)-(iv) above were taken, is generic to an *in vitro* or *in vivo* process. It is noted that on February 2, 2001, independent claim 27 (detection in an organism) was amended to depend from independent claim 3.

The examiner has stated that Group I, which includes claims 1, 2, 4, 5, 8-25, 39, is drawn to a method of qualitative and/or quantitative detection of analytes in liquid/solid phases using ferromagnetic or ferrimagnetic substances as labels and that Group II, which include claim(s) 3, 6, 7 , is drawn to a method of quantitative and/or qualitative detection of analytes in immunoassays or other binding assays using magnetic field sensors and external magnetic field.

However, the two groups at a minimum overlap since there is no requirement that Group I exclude an external magnetic field. It is also noted that both groups are detecting

analytes in liquid or solid phases which are labeled and both groups use ferromagnetic or ferrimagnetic labels. Also, as noted above and in JP 3220442, "the magnetic field is stopped before measuring the remanent magnetic flux". This statement from the prior art was originally cited in a 35 U.S.C. 102(b) rejection by the examiner for Group I claims. Therefore the examiner by using this statement in a rejection for Group I is stating that an external magnetic field can be part of the process for Group I as well as Group II.

As written, Group II is a method which is encompassed in Group I. The separation of Groups I and II as presented by the examiner does not demonstrate a difference in the methods nor does it preclude a magnetic field being used in the Group I method. They are united by having the same methodology which includes labeling with a ferromagnetic or ferrimagnetic substance and measuring the remanent magnetization of the sample. The same analogy applies to Groups III and IV for the method of detection of analytes in an organism. Group IV is encompassed in Group III. Thus the Lack of Unity as presented by the second examiner was in error with respect to the number of inventive groups.

As presently amended not only does Group I encompass Group II but it also encompasses Groups III and IV since there is no difference in the method performed *in vitro* or *in vivo* . Both use the same method of detection of analytes in a homogeneous immunoassay. As such, neither is patentably distinct from the other and Lack of Unity is no longer present.

DESCISION

Applicants' petition is GRANTED for the reasons set forth above.

Claims 1-3,5-18, 22-32, 35-42 are rejoined.

The application will be forwarded to the examiner for further consideration not inconsistent with this decision.

There is not fee for this petition and the petition fee paid will be credited to applicants' Deposit Account No. 13-3402, as directed.

Should there be any question to this decision, please contact William R. Dixon Jr., by mail addressed to: Director, Technology Center 1600, PO Box 1450, Alexandria, VA 22313-1450, or by telephone (703) 308-3824 or by facsimile transmission at (703) 305-7230.

Jasemine C. Chambers

Jasemine C. Chambers
Director, Technology Center 1600